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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,777	07/24/2001	Jeffrey Browning	A070US	3867

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EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/911,777	BROWNING ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-50* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Restriction Requirement

1. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-6 and 8-9, drawn to a method of stimulating B-cell growth, stimulating immunoglobulin production, co-stimulating B-cell growth and immunogloubulin production and stimulating dendritic cell-induced B-cell growth and maturation in an animal comprising the step of administering a therapeutically effective amount of a BAFF ligand or an active fragment thereof, classified in Class 514, subclass 2.

II. Claims 1-6 and 8-9, drawn to a method of stimulating B-cell growth, stimulating immunoglobulin production, co-stimulating B-cell growth and immunogloubulin production and stimulating dendritic cell-induced B-cell growth and maturation in an animal comprising the step of administering a therapeutically effective amount of a BAFF ligand or an active fragment thereof and an anti-T antibody, classified in Class 424, subclass 140.1 and Class 514, subclass 2.

III. Claims 1-6 and 8-9, drawn to a method of stimulating B-cell growth, stimulating immunoglobulin production, co-stimulating B-cell growth and immunogloubulin production and stimulating dendritic cell-induced B-cell growth and maturation in an animal comprising the step of administering a therapeutically effective amount of a BAFF ligand or an active fragment thereof and a CD40 ligand, classified in Class 514, subclass 2.

IV. Claims 1-9, drawn to a method of stimulating B-cell growth, stimulating immunoglobulin production, co-stimulating B-cell growth and immunogloubulin production and stimulating dendritic cell-induced B-cell growth and maturation in an animal comprising the step of administering a therapeutically effective amount of a BAFF ligand or an active fragment thereof and an anti-CD40 ligand molecule, classified in Class 424, subclass 140.1; Class 514, subclass 2.

V. Claims 10-16, drawn to a method of inhibiting B-cell growth, inhibiting immunoglobulin production, co- inhibiting B-cell growth and immunogloubulin production and inhibiting dendritic cell-induced B-cell growth and maturation in an animal comprising the step of administering a therapeutically effective amount of an anti-BAFFA ligand molecule or an active fragment thereof, classified in Class 424, subclass 140.1.

VI. Claims 10-15, drawn to a method of inhibiting B-cell growth, inhibiting immunoglobulin production, co- inhibiting B-cell growth and immunogloubulin production and inhibiting dendritic cell-induced B-cell growth and maturation in an animal comprising the step of administering a therapeutically effective amount of a recombinant, inoperative BAFF ligand molecule or an active fragment thereof, classified in Class 514, subclass 2 and 424, subclass 140.1.

VII. Claims 10-16, drawn to a method of inhibiting B-cell growth, inhibiting immunoglobulin production, co- inhibiting B-cell growth and immunogloubulin production and inhibiting dendritic cell-induced B-cell growth and maturation in an animal comprising the step of administering a therapeutically effective amount of an antibody specific for BAFF ligand or an active fragment thereof, classified in Class 424, subclass 140.1 and Class 424, subclass 140.1.

VIII. Claims 10-13, drawn to a method of inhibiting B-cell growth, inhibiting immunoglobulin production, co- inhibiting B-cell growth and immunogloubulin production and inhibiting dendritic cell-induced B-cell growth and maturation in an animal comprising the step of administering a therapeutically effective amount of an antibody specific for BAFF ligand receptor or an epitope thereof, classified in Class 424, subclass 140.1; Class 514, subclass 2.

IX. Claims 17 and 20-21, drawn to a method of treatment of an autoimmune disease comprising the step of administering a therapeutically effective amount of a BAFF ligand or an active fragment thereof, classified in Class 514, subclass 2.

X. Claims 17 and 20-21, drawn to a method of treatment of an autoimmune disease comprising the step of administering a therapeutically effective amount of a BAFF ligand or an active fragment thereof and an anti-T antibody, classified in Class 514, subclass 2 and Class 424, subclass 140.1.

XI. Claims 17, and 20-21, drawn to a method of treatment of an autoimmune disease comprising the step of administering a therapeutically effective amount of a BAFF ligand or an active fragment thereof and a CD40 ligand, classified in Class 514, subclass 2.

XII. Claims 17 and 20-22, drawn to a method of treatment of an autoimmune disease comprising the step of administering a therapeutically effective amount of a BAFF ligand or an active fragment thereof and an anti CD40 ligand molecule, classified in Class 514, subclass 2 and Class 424, subclass 140.1.

XIII. Claims 17 and 23-25, drawn to a method of treatment of an autoimmune disease comprising the step of administering a therapeutically effective amount of an anti-BAFF ligand molecule or an active fragment thereof, classified in Class 424, subclass 140.1.

XIV. Claims 17 and 20-21, drawn to a method of treatment of an autoimmune disease comprising the step of administering a therapeutically effective amount of a recombinant, inoperative BAFF ligand molecule or an active fragment thereof, classified in Class 514, subclass 2.

XV. Claims 17 and 23-25, drawn to a method of treatment of an autoimmune disease comprising the step of administering a therapeutically effective amount of an antibody specific for BAFF ligand or an active fragment thereof, classified in Class 424, subclass 140.1.

XVI. Claims 17 and 26, drawn to a method of treatment of an autoimmune disease comprising the step of administering a therapeutically effective amount of an antibody specific for BAFF ligand receptor or an epitope thereof, classified in Class 424, subclass 140.1.

XVII. Claims 18-21, drawn to a method of treating a disorder related to BAFF-ligand comprising introducing into a desired cell a therapeutically effective amount of a vector containing a gene encoding for a BAFF-related molecule and expressing said gene in said cell, wherein the BAFF-related molecule is a BAFF ligand or an active fragment thereof, classified in Class 514, subclass 44.

XVIII. Claims 18-21, drawn to a method of treating a disorder related to BAFF-ligand comprising introducing into a desired cell a therapeutically effective amount of a vector containing a gene encoding for a BAFF-related molecule and expressing said gene in said cell, wherein the BAFF-related molecule is a BAFF ligand or an active fragment thereof and an anti-T antibody, classified in Class 514, subclass 44.

XIX. Claims 18-21, drawn to a method of treating a disorder related to BAFF-ligand comprising introducing into a desired cell a therapeutically effective amount of a vector containing a gene encoding for a BAFF-related molecule and expressing said gene in said cell, wherein the BAFF-related molecule is a BAFF ligand or an active fragment thereof and a CD40 ligand, classified in Class 514, subclass 44.

XX. Claims 18-22, drawn to a method of treating a disorder related to BAFF-ligand comprising introducing into a desired cell a therapeutically effective amount of a vector containing a gene encoding for a BAFF-related molecule and expressing said gene in said cell, wherein the BAFF-related molecule is a BAFF ligand or an active fragment thereof and an anti-CD40 ligand molecule, classified in Class 514, subclass 44.

XXI. Claims 18-19 and 23-25, drawn to a method of treating a disorder related to BAFF-ligand comprising introducing into a desired cell a therapeutically effective amount of a vector containing a gene encoding for a BAFF-related molecule and expressing said gene in said cell, wherein the BAFF-related molecule is an anti-BAFF ligand molecule or an active fragment thereof, classified in Class 514, subclass 44.

XXII. Claims 18-21, drawn to a method of treating a disorder related to BAFF-ligand comprising introducing into a desired cell a therapeutically effective amount of a vector containing a gene encoding for a BAFF-related molecule and expressing said gene in said cell, wherein the BAFF-related molecule is a recombinant, inoperative BAFF ligand molecule or an active fragment thereof, classified in Class 514, subclass 44.

XXIII. Claims 18-19 and 23-25, drawn to a method of treating a disorder related to BAFF-ligand comprising introducing into a desired cell a therapeutically effective amount of a vector containing a gene encoding for a BAFF-related molecule and expressing said gene in said cell, wherein the BAFF-related molecule is an antibody specific for BAFF ligand or an active fragment thereof, classified in Class 514, subclass 44.

XXIV. Claims 18-19 and 26, drawn to a method of treating a disorder related to BAFF-ligand comprising introducing into a desired cell a therapeutically effective amount of a vector containing a gene encoding for a BAFF-related molecule and expressing said gene in said cell, wherein the BAFF-related molecule is an antibody specific for BAFF ligand receptor or an epitope thereof, classified in Class 514, subclass 44.

XXV. Claim 27, drawn to a method of inducing a cell death comprising the administration of an agent capable of interfering with the binding of a BAFF-ligand to a receptor, classified in Class 514, subclass 2, and Class 424, subclass 140.1.

XXVI. Claims 28 and 32, drawn to a method of treating, suppressing or altering an immune response involving a signaling pathway between a BAFF-ligand and its receptor comprising the step of administering an effective amount of an agent capable of interfering with the association between the BAFF-ligand and its receptor, classified in Class 514, subclass 2, and Class 424, subclass 140.1.

XXVII. Claim 29, drawn to a method of inhibiting inflammation comprising the step of administering a therapeutically effective amount of an antibody specific for a BAFF-ligand or an active fragment thereof, classified in Class 424, subclass 140.1.

XXVIII. Claim 30, drawn to a method of inhibiting inflammation comprising the step of administering a therapeutically effective amount of an antibody specific for a BAFF-ligand receptor or epitope thereof, classified in Class 424, subclass 140.1.

XXIX. Claim 31, drawn to a method of regulating hematopoietic cell development comprising the step of administering a therapeutically effective amount of a BAFF-ligand or an active fragment thereof, classified in Class 514, subclass 2.

XXX. Claims 33-37 and 39-40, drawn to method of treating hypertension in an animal comprising the step of administering a therapeutically effective amount of a B-cell growth inhibitor, wherein the B-cell growth inhibitor is an anti-BAFF ligand molecule or an active fragment thereof, classified in Class 424, subclass 140.1.

XXXI. Claims 33-34 and 39-40, drawn to method of treating hypertension in an animal comprising the step of administering a therapeutically effective amount of a B-cell growth inhibitor, wherein the B-cell growth inhibitor is a recombinant, inoperative BAFF ligand molecule or an active fragment thereof, classified in Class 514, subclass 2.

XXXII. Claims 33-37 and 39-40, drawn to method of treating hypertension in an animal comprising the step of administering a therapeutically effective amount of a B-cell growth inhibitor, wherein the B-cell growth inhibitor is an antibody specific for BAFF ligand or an active fragment thereof, classified in Class 424, subclass 140.1.

XXXIII. Claims 33-34 and 38-40, drawn to method of treating hypertension in an animal comprising the step of administering a therapeutically effective amount of a B-cell growth inhibitor, wherein the B-cell growth inhibitor is an antibody specific for BAFF ligand receptor or an epitope thereof, classified in Class 424, subclass 140.1.

XXXIV. Claim 41-43, drawn to method of treating cardiovascular disorders in an animal comprising the step of administering a therapeutically effective an anti-BAFF ligand molecule or an active fragment thereof, classified in Class 424, subclass 140.1.

XXXV. Claim 41-43, drawn to method of treating cardiovascular disorders in an animal comprising the step of administering a therapeutically effective a recombinant, inoperative BAFF ligand molecule or an active fragment thereof, classified in Class 424, subclass 140.1, and Class 514, subclass 2.

XXXVI. Claim 41-43, drawn to method of treating cardiovascular disorders in an animal comprising the step of administering a therapeutically effective an antibody specific for BAFF ligand or an active fragment therof, classified in Class 424, subclass 140.1.

XXXVII. Claim 41-43, drawn to method of treating cardiovascular disorders in an animal comprising the step of administering a therapeutically effective an antibody specific for BAFF ligand receptor or an epitope thereof, classified in Class 424, subclass 140.1.

XXXVIII. Claims 44-45, drawn to method of treating renal disorders in an animal comprising the step of administering a therapeutically effective amount of an anti-BAFF ligand molecule or an active fragment thereof, classified in Class 424, subclass 140.1.

XXXIX. Claims 44-45, drawn to method of treating renal disorders in an animal comprising the step of administering a therapeutically effective amount of a recombinant, inoperative BAFF ligand molecule or an active fragment thereof, classified in Class 424, subclass 140.1, and Class 514, subclass 2.

XL. Claims 44-45, drawn to method of treating renal disorders in an animal comprising the step of administering a therapeutically effective amount of an antibody specific for BAFF ligand or an active fragment thereof, classified in Class 424, subclass 140.1.

XLI. Claims 44-45, drawn to method of treating renal disorders in an animal comprising the step of administering a therapeutically effective amount of an antibody specific for BAFF ligand receptor or an epitope thereof, classified in Class 424, subclass 140.1.

XLII. Claim 46, drawn to a method of treating B-cell lympho-proliferate disorders comprising the step of administering a therapeutically effective amount of an anti-BAFF ligand molecule or an active fragment thereof, classified in Class 424, subclass 140.1.

XLIII. Claim 46, drawn to a method of treating B-cell lympho-proliferate disorders comprising the step of administering a therapeutically effective amount of a recombinant, inoperative BAFF ligand molecule or an active fragment thereof, classified in Class 424, subclass 140.1, and Class 514, subclass 2.

XLIV. Claim 46, drawn to a method of treating B-cell lympho-proliferate disorders comprising the step of administering a therapeutically effective amount of an antibody specific for BAFF ligand or an active fragment thereof, classified in Class 424, subclass 140.1.

XLV. Claim 46, drawn to a method of treating B-cell lympho-proliferate disorders comprising the step of administering a therapeutically effective amount of an antibody specific for BAFF ligand receptor or an epitope thereof, classified in Class 424, subclass 140.1.

XLVI. Claims 47-50, drawn to a method of treating B-cell production in the treatment of immunosuppressive diseases comprising the step of administering a BAFF ligand or an active fragment thereof, classified in Class 514, subclass 2.

XLVII. Claims 47-50, drawn to a method of treating B-cell production in the treatment of immunosuppressive diseases comprising the step of administering a BAFF ligand or an active fragment thereof and an anti-T antibody, classified in Class 514, subclass 2, and Class 424, subclass 140.1.

XLVIII. Claims 47-50, drawn to a method of treating B-cell production in the treatment of immunosuppressive diseases comprising the step of administering a BAFF ligand or an active fragment thereof and a CD40 ligand, classified in Class 514, subclass 2 and Class 424, subclass 140.1.

XLIX. Claims 47-50, drawn to a method of treating B-cell production in the treatment of immunosuppressive diseases comprising the step of administering a BAFF ligand or an active fragment thereof and an anti-CD40 ligand molecule, classified in Class 514, subclass 2 and Class 424, subclass 140.1.

L. Claims 47-50, drawn to a method of treating B-cell production in the treatment of immunosuppressive diseases comprising the step of administering an anti-BAFF ligand molecule or an active fragment thereof, classified in Class 424, subclass 140.1.

LI. Claims 47-50, drawn to a method of treating B-cell production in the treatment of immunosuppressive diseases comprising the step of administering a recombinant, inoperative BAFF ligand molecule or an active fragment thereof, classified in Class 514, subclass 2.

LII. Claims 47-50, drawn to a method of treating B-cell production in the treatment of immunosuppressive diseases comprising the step of administering an antibody specific for BAFF ligand or an active fragment thereof , classified in Class 424, subclass 140.1.

LIII. Claims 47, 49-50, drawn to a method of treating B-cell production in the treatment of immunosuppressive diseases comprising the step of administering an antibody specific for BAFF ligand receptor or an epitope thereof, classified in Class 514, subclass 2 and Class 424, subclass 140.1.

3. Groups I-LIII are different methods. A method of stimulating, a method of co-stimulating a method of inhibiting, a method of co-inhibiting, a method of inducing, a method of regulating and a method of treating differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

4. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Species Election

5. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

> If anyone of Group XLV-LIV is elected, applicant is required to elect a method of treating B-cell production in the treatment of immunosuppressive diseases wherein the disease is (a) HIV or (b) an organ transplantation. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

6. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Applicant is reminded that upon the cancellation of Claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one Claims remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (703) 306-3472. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
May 16, 2002

Christina Chan
CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP ~~1800~~ 1640